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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,721	04/27/2005	Tomoya Takahashi	00005.001260.	8744

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
12/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,721	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/20/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 and 15-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2008 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the arguments filed on 10/20/2008.

3. Claims 13 and 15-29 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 10/20/2008 regarding the rejection of claims 13 and 15-29 made by the Examiner under 35 USC 103(a) over Kobayashi et al. (EPP 1304323) in view of Coirre et al. (US 3932638) and Takagi et al. (US 3988466) have been fully considered but they are not found persuasive.

5. In response to the 103(a) rejection, Applicant asserts:

A) The claims do not recite treating wounds, but rather treating atopic dermatitis.

6. With respect to assertion A, it is duly noted that the claims do not recite treating wounds. The teaching of Kobayashi indicates that hydroxyproline and its derivatives are useful for combating atopic dermatitis. Kobayashi is lacking a suggestion of administering the compounds orally. These very same compounds are known to be suitable for oral administration to

accelerate wound healing by accelerating protein synthesis. It would have been obvious to an ordinarily skilled artesian to at least try administering the compounds to a subject with a reasonable expectation that it would treat atopic dermatitis. It is the position of the Examiner that it is well known in the art that upon oral administration of a compound the compounds concentration in the compound will increase. Consequently, the drugs presence in the blood plasma will enable the compound to be distributed to all organs of the body, the skin included. It would not have been a great leap of science to attempt the instantly claimed method, especially in view of the fact that the compounds recited by Kobayashi were already known to be safe to administer to humans for similar pharmacological purposes. Applicants argument is not persuasive.

Maintained Rejections, of Record
Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 13 and 15-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (EP 1304323; of record, see IDS) in view of Coirre et al. (US 3932638; of record) and Takagi et al. (US 3988466; of record).**

9. Kobayashi is drawn to epidermal ceramide synthesis accelerators and agents for improving atopic dermatitis which employs the active ingredients hydroxyproline or an N-acyl derivative hydroxyproline, or a salt thereof (see abstract). It is disclosed that the hydroxyproline or the N-

acyl hydroxyproline derivative is present in the medicament at a weight percentage of 0.1 to 10% from once to several times per day (see page 6, lines 52-55; see instant claims 15-17). It is taught that the N-acyl derivatives include an acyl group having 1 to 24 carbons, more preferably 1 to 12 carbons and most preferably 1 to 6 carbons. Specific examples include formyl, acetyl, butyryl, and decanoyl groups (see page 4, lines 8-12; see instant claims 19-23). The compounds are delivered in a form of a medicament (see page 5, lines 13-15).

10. Kobayashi fails to specifically teach the hydroxyproline and the N-acylated hydroxyproline derivative as being orally administered.

11. Coirre is drawn to using derivatives of L-hydroxyproline for the treatment of inflammation and wound healing (see abstract). An exemplified derivative is N-acetyl-L-hydroxyproline (see column 1, lines 55-60 and column 2, lines 57-58) which is taught to be useful for treating conditions affecting wounds by accelerating protein synthesis to stimulate the healing process (see column 1, lines 40-45). It is disclosed that N-acetyl-L-hydroxyproline can be delivered orally in a variety of forms including tablets and capsules (see column 9, lines 35-40; see instant claims 13 and 18). A patient may be administered a therapeutically effective amount of the compound from about 300 to 900 mg/day (see column 9, lines 60-62; see instant claims 24-29).

12. Takagi is drawn to the prevention of gastric lesions through the administration of amino acids (see abstract). It is taught the L-hydroxyproline is suitable for oral administration in an amount from 1g to 10g/dose (see claims 1 and 3; see instant claims 13 and 18).

13. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Kobayshi, Coirre and Takagi with a reasonable

expectation for success in arriving at a method for treating atopic dermatitis by orally administering hydroxyproline or N-acylated hydroxyproline derivative. The significance of Kobayshi is that it teaches hydroxyproline and N-acylated hydroxyproline derivatives such as N-acetyl-hydroxyproline and N-butyryl-hydroxyproline are useful for accelerating ceramide synthesis thereby reducing the unpleasant effects of atopic dermatitis. Kobayashi fails to teach the compounds as being suitable for oral administration. Coirre teaches that hydroxyproline derivatives such as N-acetyl-hydroxyproline are suitable for oral administration. As noted above, it is the position of the Examiner that by orally administering these compounds, they will consequently become present in the blood plasma and be distributed to all organs of the body, including the skin. Thus, one would have a reasonable expectation for success in treating atopic dermatitis by orally administering hydroxyproline and its derivatives. With respect to the recited weight percentages, these are also obvious. It would have been within the purview to one of ordinary skill in the art, upon combining the references, to adjust the relative amounts of ingredients with the goal of arriving at a medicament with the greatest efficacy in treating atopic dermatitis. Therefore, a method of treating atopic dermatitis by administering hydroxyproline and its salts orally is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

14. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
December 10, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643